AutoMedx
MEDICAL SUPPORT TECHNOLOGY

SAVe

Simplified Automated Ventilator

Operations Manual

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AutoMedx's warranty is neither assignable nor transferable.

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Glossary

CO_2	Carbon dioxide
ET Tube	Endotracheal Tube
O_2	Oxygen
PEEP	Positive end expiratory pressure
SAVe	Simplified Automated Ventilator
PIP	Peak Inspiratory Pressure

Introduction

Medics receive minimal respiratory training and frequently lack the equipment needed to provide ventilatory support when mechanical ventilation is necessary. Nonetheless, medics often perform the diagnosis and treatment of respiratory failure in the battlefield environment. Ventilation is typically maintained by the use of a bag-valve-mask (Figure 1). While these devices are light and easy to use, they deliver variable respiratory support, which is dependent on the skill of the provider, and require that the caregiver stay with the victim at all times. This prevents the medic from attending other injuries, treating additional injured patients, or further assisting in the evacuation.

Figure 1: BVM: Bag-valve-mask

Emergency transport ventilators are much too cumbersome and difficult to operate in the far forward environment. AutoMedx has developed a self-contained, air pump driven micro-ventilator, the Simplified Automated Ventilator (SAVe), which meets the need for simple pre-hospital ventilatory support and shows tremendous promise in revolutionizing ventilator capability on the battlefield. The SAVe is a robust, portable, analog circuit controlled ventilator that utilizes discrete logic rather than software to operate. Designed for extreme functional simplicity with minimal operator intervention, the SAVe provides up to 5.75 hours of operation on a single battery charge. The device is 6.25" x 6.75" x 2.5" and weighs 3.1 lbs.

There are presently two SAVe models. Both models deliver a set tidal volume at a set respiratory rate. It is up to the prescribing physician which model is most appropriate for his or her patient. All SAVe models are considered FDA Class II devices.

	Model: 550 X 10	**Model: 600 X 10**
Tidal Volume	550 mL / breath	600 mL / breath
Respiratory Rate	10 breaths / minute	10 breaths / minute
Peak Inspiratory Pres	30 cmH_2O	38 cmH_2O
Inspiratory Time	2.10 seconds	2.25 seconds
Expiratory Time	4.00 seconds	3.85 seconds
Duration	Up to 5.75 hours	Up to 5.5 hours

Unlike other field-ventilators, the SAVe does not require a compressed gas source to operate. Instead it uses a rechargeable battery to drive a pump which delivers ambient air to the patient. Depending on the model the SAVe can operate between 5.5 – 5.75 hours on a single charge. When the battery is low the unit can be connected to its external power supply. This will run the unit as well as recharge the battery.

NOTE: Operation time is materially affected by many factors. Please see section on Battery Power Level for more information.

How it works

The SAVe's pneumatic subsystem uses an internal air pump to deliver ambient air to the patient. During the inhalation cycle, ambient air is drawn into the pump through the air input port. If needed, supplemental O_2 or medical grade air may be connected to an additional port.

As air is pushed from the pump into the internal manifold, a pneumatically connected pressure sensor monitors the pressure of the air delivered to the patient. The air manifold interfaces to the patient breathing circuit by way of a standard 22mm (outside diameter) port. The patient breathing circuit contains a bi-directional valve that directs air to the patient when the pump is running. When the pump is not pushing air, the valve allows the patient to exhale to ambient through the valve's exhalation port. The design of the breathing circuit allows the patient to breathe ambient air with minimal resistance from the valve through its exhaust port if a spontaneous breath occurs during the ventilator's exhale state or even if the unit is powered off.

The second pressure sensor is connected through tubing to a sampling port between the bi-directional valve and the patient. This second pressure sensor monitors the patient's airway pressure, assuring the patient's lung pressure during the entire breathing cycle is within expected limits. An additional colorimetric or chemical capnography sensor to monitor ventilation efficacy may be connected to the patient breathing circuit in-line between the valve and the patient.

The SAVe consists of numerous safety and alarm features to prevent harm to the patient and alert the medic immediately of a problem. These features include monitoring for a disconnection of the patient circuit, a blockage in the airway, and excessive PEEP. If the patient's lung pressure reaches the Peak Inspiratory Pressure (PIP) limit during inhalation (either due to small lung volume or external lung compression), the SAVe immediately enters into an exhale cycle.

When the SAVe should be used / indication for use statement

The SAVe is intended for use on adults that need ventilatory support. Specifically, the SAVe is intended to provide short term ventilatory support for individuals during CPR or when positive-pressure ventilation is required to manage acute respiratory failure. The SAVe device is appropriate for individuals that weigh at least 45 kilograms. It is intended to be used in field hospitals, transport and pre-hospital environments.

When the SAVe should not be used

The SAVe is not intended for long-term use. Once the patient has reached a higher echelon of care and a hospital-grade ventilator is available, the SAVe should be replaced.

The SAVe is not intended for children or adults weighing less than 45 kilograms.

The SAVe should not be used without a medic nearby to respond in the event one of the alarms is triggered.

Risks and benefits

The SAVe was developed to improve survival rates of soldiers suffering acute respiratory failure by providing unparalleled access to mechanical ventilation on the battlefield. Its purpose is to enable a medic, combat life saver, or other first responder with limited training to provide life saving ventilation until the patient can be evacuated to a higher echelon of care. To that end, the device is easy to use, lightweight, and withstands the rigors of the battlefield. The SAVe utilizes a single Tidal Volume and Respiratory Rate. Despite the lack of specificity found in other emergency transport or critical care ventilators, the SAVe will offer adequate, safe, and consistent respiratory care until the patient reaches a higher echelon of care.

The SAVe has a number of benefits over a bag-valve-mask (BVM). First, it offers a breath-to-breath consistency that is not achievable with a BVM. This is especially important during high stress situations. The SAVe will ensure the patient receives a consistent tidal volume at a consistent rate. Second, the SAVe, unlike a BVM, frees up the medic to address other injuries, attend to other patients or further assist in the evacuation. Third, the SAVe will provide 5 plus hours of ventilation on a full charge. It is impractical to expect a medic to be able to provide resuscitation manually for that duration with a BVM.

The SAVe uses a rechargeable battery driven pump to deliver ambient air to the patient. It is completely self contained and does not need compressed air to operate. The SAVe accepts low pressure supplemental oxygen but does not require it. High pressure oxygen tanks pose a conflagration hazard on the battlefield, significantly increase the overall footprint of the device and only provide air for a short period of time.

Although the SAVe is a hands-free device, the medic administering care must always remain within earshot of the device to listen for any alarms that may occur. The SAVe is designed to prevent immediate harm to the patient if a problem should occur. In addition to sounding an alarm, the unit will safely cut-off power to the pump when the delivery of additional air would cause immediate harm to the patient. Although this is a safety feature that protects the patient, a medic needs to respond quickly to fix the fault that triggered the alarm or the patient may die from a lack of air.

Expectations of the device and the procedure associated with the device

When the SAVe is turned on it takes several seconds to initialize before it begins to deliver air. In accordance with FDA Guidelines, the tidal volume is within +/- 10% of the stated tidal volume and within 1 breath per minute of the stated respiratory rate. Depending on the model, the SAVe can operate between 5.5 and 5.75 continuous hours on a fully charged battery. If necessary, the SAVe can operate for longer durations if external power is supplied (see section on Operating and Recharging using an External Power Source).

The SAVe is tested prior to leaving the manufacturing facility to ensure compliance with the stated operating specifications. The SAVe should be fully recharged every 6 months and tested to ensure it operates properly. A complete diagnostic check should be completed on the unit every 12 months or after 2000 hours of run-time, whichever comes first.

General warnings and cautions

WARNING: Electric shock hazard, do not open the enclosure casing.

WARNING: Do not operate the SAVe prior to reading instructions contained within this manual.

WARNING: The exact power supply provided must be used with the SAVe. (Manufacturer: Reliance; Model Number: MPP30-15-M-ROW-US-77-CP).

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

CAUTION: Do not get water, oil, grease, sand or other particulates in the ports.

CAUTION: Service is to be performed by qualified biomedical equipment technicians only.

CAUTION: Do not allow oil and grease to enter the SAVe.

CAUTION: Internal components are susceptible to damage from static discharge.

CAUTION: The device may deliver less than its stated tidal volume for several minutes if stored in temperatures at or below freezing.

CAUTION: Potential electromagnetic interference at levels greater than 20 V/m. Avoid use of the device in unknown environments that may have high electromagnetic levels.

Importance of the need to adhere to instructions

The SAVe is a life-supporting medical device. Improper use of the device could lead to harm of the patient. Suppressing, neglecting or otherwise not responding quickly to alarms could cause serious harm or death.

The SAVe Unit and Accessories

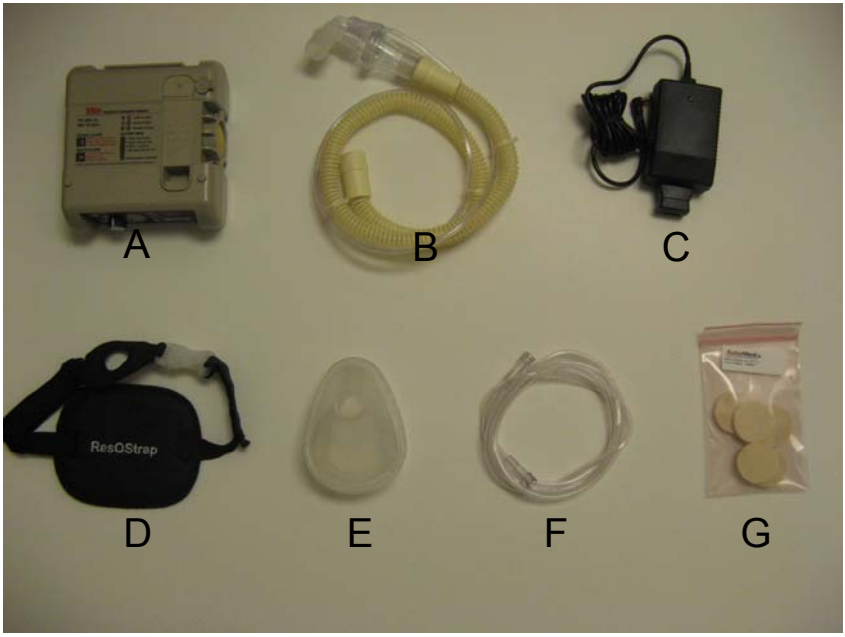


Figure 2: SAVe Unit and Accessories

The following products and accessories are to be used with the SAVe:

A. The Simplified Automated Ventilator – Primary Unit
B. Single-Use Patient Circuit and Pressure Tubing
C. External power supply and AC plug
D. ResQStrap (used to secure mask to patient)
E. Single Patient Use Ventilation Mask
F. Supplemental O_2 Tubing
G. Debris filters (pack of 5)
H. $EtCO_2$ (not depicted above)

Setting up and Operating the SAVe

Figure 3. Top View of SAVe.

Figure 4: Front View of SAVe

Installing the Debris Filter

The SAVe is intended for use on the battlefield and other pre-hospital environments. Therefore, it is necessary for a filter to be installed into the ventilator's air intake port to prevent dirt, sand, or other debris and contaminates from entering the ventilator, potentially damaging the ventilator or patient.

The Air Intake Port (**Figure 5**) is located on the right side of the ventilator (if you are looking at the unit's main control panel, **Figure 4**). The debris filter (**Figure 6**) is a foam disk approximately 1.6 inches in diameter and 0.375 inches thick. This filter material has been carefully chosen because it will not interfere with the ventilator's airflow. Only debris filters supplied by AutoMedx should be used in the SAVe.

Figure 5: Air Intake Port

Figure 6: Debris Filter

Once the debris filter has been properly installed (**Figure** 7) it should appear flush against the side of the ventilator housing. The SAVe should never be used without the debris filter installed. The debris filter should be cleaned or replaced whenever visible buildup of dirt is observed or it has been exposed to biomaterial such as blood or vomitus. AutoMedx recommends cleaning or replacing the debris filter after each patient use.

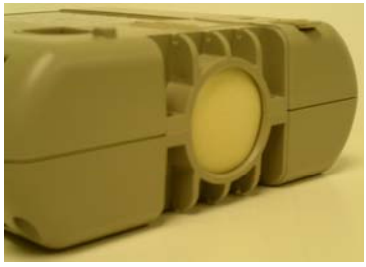


Figure 7. View of SAVe with debris filter properly installed.

Connecting the Patient Mask to the Ventilator

The purpose of the SAVe is to deliver air to a patient's lungs while the patient is unable to breath on their own. This is generally accomplished by connecting the ventilator to a breathing mask. The preferred method of securing the mask to the patient is using the ResQStrap. See the pictures below. If a mask is being used instead of Endotracheal tube special care must be given to ensure the head remains tilted. If the head tilts forward, the airway may become compromised. **Do not suppress the alarms unless absolutely necessary especially while using a mask.** A material amount of air may leak without triggering the alarm so ensure there is a good seal. Only masks sold by AutoMedx or an authorized distributor should be used. **Under no circumstances use a mask that has any type of filter or one way valve in it, or contains an open oxygen/air port.**

Figure 8. Patient mask with ResQStrap.

Figure 9. Patient mask connected to patient circuit.

Figure 10. Mask connected to patient

Figure 11. Connecting the patient circuit to the ventilator.

The mask is attached to the ResQStrap which is tightened using Velcro straps on each side of the mask. This will help secure the mask firmly against the patient's mouth. Once the mask is properly connected (**Figure 10**) and placed on the patient, the other end of the patient circuit is connected to the ventilator (**Figure 11**). The mask is NOT for use in temperatures above 40°C (104°F).

Using the SAVe with an Endotracheal Tube

The SAVe may be attached directly to an endotracheal tube (**Figure 12**) which has been properly inserted into the patient. Always ensure the endotracheal tube is properly inserted into the patient before connecting the patient circuit.

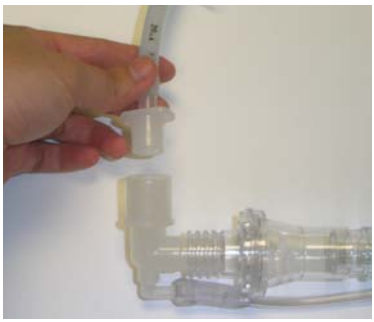


Figure 12. Connecting Endotracheal tube to patient circuit.

Figure 13. Endotracheal tube connected to patient circuit.

Connecting the End-Tidal CO2 Detector

It is strongly recommended that the Care Provider install an $EtCO_2$ detector (**Figure 14**) in-line with the patient circuit between the valve and the patient. This is done by connecting the $EtCO_2$ to the 90 degree elbow. The material inside the viewing window will turn purple if the patient's exhale includes carbon dioxide (CO_2). The presence of CO_2 in a patient's exhaled air is a good indicator that a proper respiratory exchange is occurring in the patient's lungs. If the material doesn't turn purple, ensure that the patient is properly intubated if an ET Tube has been inserted or that the mask has a tight seal. In addition, check to ensure the patient has a pulse.

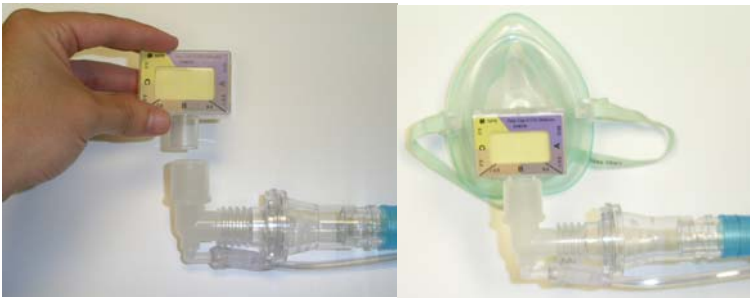


Figure 14. $EtCO_2$ Detector (left), connect to patient circuit (center), and connect to patient mask (right).

Once activated, the $EtCO_2$ sensor lasts approximately 1 hour. The sensor may not be refurbished or reused and should be properly disposed of once expended. To ensure compatibility and proper operation, only use $EtCO_2$ detectors purchased through AutoMedx or its authorized distributors. All instructions and directions included with the sensor should be followed. Should the ventilator be in use more than one hour, it is recommended that the CO_2 sensor be disposed of properly and a replacement installed.

With the debris filter installed, the mask and ventilator tubing connected the SAVe is now ready for patient use.

Figure 15. View of SAVe ready for patient use.

Operational Modes

The SAVe has one primary mode of operation: ON. All switch positions (**Figure 16**) other than the OFF (O) position will cause the ventilator to function. Because battlefield use may require suppression of audible or visual alarms, additional alarm configurations are provided. The ON (I) position will activate the ventilator and both visual and audible alarms. The following position will operate visual alarms; however, audible alarms will be suppressed. The following switch position will activate audible alarms and suppress visual alarms. Finally, the last setting suppresses all audible and visual alarms. Remember alarms should only be fully suppressed when absolutely necessary. Icons at each position have been provided as a visual reminder.

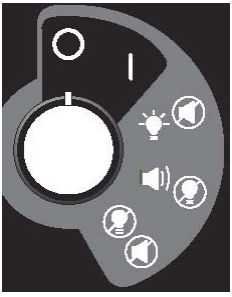


Figure 16. Operational switch positions.

When operating with all alarms suppressed, the patient must be constantly monitored, as there is no means for the SAVe to alert nearby personnel of a patient related or device related error condition. This is especially true if using a mask as the airway could become compromised by the head tilting forward. If an alarm condition should occur, the status of the various LEDs will help the user troubleshoot the problem. Please see Indicators, Errors and Alarms section on page 16 for further details.

Securing the SAVe to the Patient

During evacuation or transport, it is strongly recommended that the SAVe be secured to the patient. The easiest method to accomplish this is to use rolled gauze (ex: Kerlix) to wrap the SAVe and patient together, generally using an arm.

When securing the SAVe to the patient, keep in mind the following:

1. Be aware of the flexibility and length of the patient breathing circuit between the SAVe and the patient mask or endotracheal tube. This tubing should retain some flexibility of movement once the SAVe has been secured.
2. Do not block the air intake port (on the side of the unit) or either of the patient circuit's valve ports (to patient and exhale).
3. Do not secure the SAVe to an injured limb.
4. Keep visual access to the error alarm icons and battery indicator LEDs.
5. Make sure the switch is oriented so that it cannot be accidentally moved.

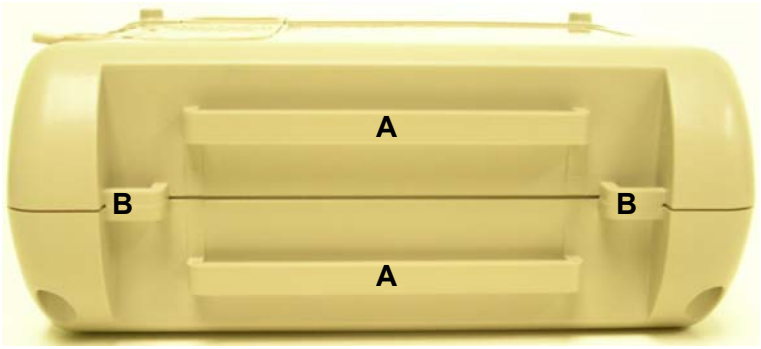


Figure 17. View of attachment points (rear panel) for SAVe.

The SAVe also provides two alternative methods of secure attachment. First, two belt loops (**Figure 17A**) are attached to the rear panel of the SAVe. A belt or strap can be run through these loops and used to tighten the SAVe against the patient. Second, two cord attachment (**Figure 17B**) loops are provided. To attach a cord(**Figure 18**) (shoelace, etc.) to this loop, pass the center of the cord through the loop on the SAVe, and then pass the ends of the cord through the loop of cord created. Tighten the cords by pulling on both ends. The free ends of the cord may now be used to tie or secure the unit.

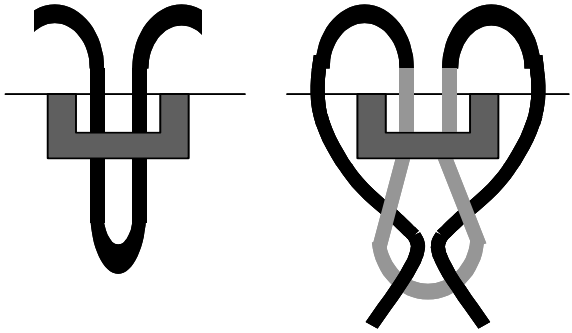


Figure 18. Connecting an attachment cord.

Using the SAVe with Supplemental Air or Oxygen

In most emergency resuscitation situations, supplemental air or oxygen may be unavailable or unnecessary; however, the SAVe provides the ability to accept supplemental air or oxygen. Standard medical grade tubing is connected from the air source's flow-regulated output valve to the supplemental air port on the SAVe (**Figure19**). The air must be regulated at the source.

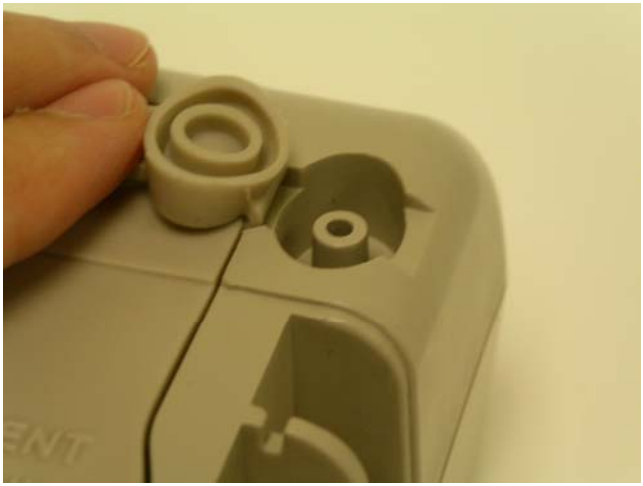


Figure 19. Connecting supplemental air or oxygen to the SAVe.

The air flowing in the supplemental port is blended with the ambient air being drawn in through the air intake port. Changing the flow rate of the air from the source will change the concentration of air delivered to the patient. The maximum acceptable flow rate from the air source is 6 liters per minute. The associated fraction of inspired oxygen (FIO_2) at different flow rates is shown in the table on the following page. Values may vary by

several percentage points. **Never deliver more than 6 LPM as it could cause harm to the device and patient.**

Flow Rate (L/min)	Oxygen Concentration (%)
0	21
1	33
2	40
4	51
6	62

Operating and recharging using an External Power Source

While the SAVe is typically battery powered, it may become necessary to operate the SAVe for durations longer than the internal battery source can provide. In these situations, the SAVe may be operated by connecting the external power supply to an outlet and the power jack on located on the front panel (**Figure 20**). When the external power source is connected and the unit is operating, the external power indicator will illuminate (unless visual alarms and indicators have been suppressed). In the event the external power supply becomes lost or damaged, contact AutoMedx for a replacement.

Figure 20. Connecting an external power source to the SAVe.

The SAVe should be fully recharged after every use. To charge the device, connect the external power supply as shown in **Figure 20**. The Power Supply can accept an AC voltage between 100 and 240V at frequencies of 50-60 Hz. The battery will lose a portion of its charge every month. A completely depleted battery takes approximately 6 hours to fully recharge. If in doubt about the state

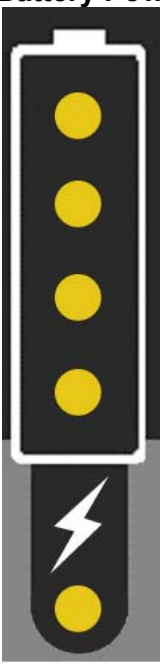
of the charge, recharge the battery. Recharge the device after it is used. Storing the device with a low charge may shorten the life of the battery. To ensure the SAVe retains at least 65% of its charge, follow the below guidelines.

Storage Temperature	Interval of charge (refresh charge)
68°F (20°C) to 86°F (30°C)	9 Months
68°F (20°C) to 86°F (30°C)	6 Months
86°F (30°C) to 104°F (40°C)	3 Months

NOTE: The SAVe internal battery is not field replaceable. Please contact AutoMedx for further instructions if the battery must be replaced.

Indicators, Errors and Alarms

Battery Power Level and High Temperature Indicator



The SAVe operates primarily from an internal, rechargeable battery. Located on the front panel of the SAVe is a battery icon with four power level indicators. The fifth LED is the external power supply indicator. When the SAVe is operating, and the visual alarms and indicators have not been suppressed, the battery icon estimates the remaining charge in the battery.

- Four lights – the SAVe is at or near full charge.
- Three lights – the SAVe has a good charge.
- Two lights – the SAVe has a low charge.
- One light (blinking) – the SAVe is nearly out of power. The SAVe should be recharged as soon as possible or replaced with a fully charged unit.

The chart below gives the approximate run time remaining for a given battery level. When the SAVe is connected to its external power supply, the external power indicator (shown to the left and resembles a lightning bolt) will illuminate, indicating the unit is being powered externally and the battery is recharging.

If all four lights are blinking then the internal temperature exceeds 60 degrees C. The SAVe is operating outside of manufacture specifications. This may cause the device to malfunction and could result in harm to the patient. The patient should be ventilated by other means.

Battery Level	Model 550x10	Model 600x10
4 Lights	4 – 5.75 hours	3.5 – 5.5 hours
3 Lights	2.75 – 4 hours	2.25 – 3.5 hours
2 Lights	1 – 2.75 hours	1 – 2.25 hours
1 Light (blinking)	Less than 60 min	Less than 60 min

NOTE: Operation time is materially affected by the following factors:

- State of charge
  - Time since last charge.
  - Temperature of battery during charging.
- Temperature of the environment where SAVe is used.
- Age of battery and number of charge / discharge cycles.
- Patient specific factors such as lung compliance and resistance (ie. Higher resistance decreases operation time as does lower lung compliance)
  For more detailed battery specifications, contact AutoMedx.

Patient Related (Repairable) Error

There are a number of conditions that may trigger the patient alarm including:

- Disconnected patient circuit anywhere between the ventilator and the mask or endotracheal tube.
- Broken or punctured patient circuit.
- Poor seal between the patient and breathing mask.
- Patient Airway is compromised.
- Patient is improperly intubated.
- A blockage of the intake port (next to debris filter).
- A blockage of the patient port (where patient circuit connects).
- A blockage of the exhaust air flow ports (valve).
- The patient is capable of breathing sufficiently enough to fight the ventilator's function.

In the event that none of these corrective actions resolves the alarm condition, replace the SAVe with a properly functioning unit as quickly as possible. The patient may require manual respiration or artificial respiration (rescue breathing) until the SAVe can be replaced. Please see the Troubleshooting section for more information.

Device Related (Non-field serviceable) Errors

In the event of a device related error, indicated by the flashing red indicator light next to the device error icon and audible alarm, immediately begin ventilating the patient by other means. The SAVe is not field serviceable for device related errors. The patient may require manual respiration or artificial respiration (rescue breathing) until the SAVe can be replaced with a properly functioning unit. Some possible failures that can lead to a device related error include the failure of internal components that control the inhalation and exhalation timing or the failure of the pump.

Please see the Troubleshooting section for more information.

Importance of the need to monitor the activity of the device

The SAVe is a life-supporting medical device. While the device is intended to operate as a hands-free unit, the ventilated patient must be monitored. DO NOT leave the SAVe alone with the patient. Improper use of the device could ultimately lead to harm of the patient. Neglecting alarms and not responding in a timely manner to a problem could leave the patient without ventilation for an extended period of time, potentially causing extreme harm or death.

Refurbishing and recharging the SAVe

Each time the SAVe is used on a patient, the following tasks need to be completed to ready the SAVe for the next patient.

1. The single-use endotracheal tube should be disposed of properly.
2. The single-use patient breathing circuit, including the valve and fitting, should be disposed of properly.
3. The pressure tube port on the SAVe should be wiped with a damp, soapy cloth and thoroughly dried with a lint-free cloth between patient uses.
4. The SAVe should be visually inspected for any damage that may affect operation. Do not use a damaged ventilator. Dirt and debris should be cleaned from the unit.
5. The debris filter should be replaced (page 8).
6. The patient mask should be cleaned or disposed of. The mask is reusable.
7. A new single patient use breathing circuit and Et-Tube and new or cleaned patient mask should be packaged and stored near the SAVe.
8. The SAVe should be fully charged. The battery is recharged by connecting the external power supply to the power jack located on the front panel (Figure 20, page 15). AutoMedx recommends only using the manufacturer provided power supply (100 - 240 VAC to 15.0 VDC). A fully discharged battery will typically take 6 hours to fully charge. Contact AutoMedx for additional battery charge / discharge characteristics.

Maintenance and cleaning

Keep the SAVe and its accessories clean at all times. Do not allow dirt, sand, debris, grease, oil, or caustic chemicals to enter, coat, or otherwise contaminate its components. Should the SAVe become wet, the unit should be dried using a lint-free cloth immediately, or once the unit is no longer in use. Under no circumstances is the SAVe to be immersed in liquid or exposed to an autoclave. Should the SAVe become immersed, discontinue use and return to manufacturer for refurbishing and testing. Under no circumstances should the SAVe be disassembled. Remove the Debris filter prior to cleaning the SAVe. Examine the insides of patient circuit tubing ports for dirt or debris. Removal of objects, if required, may be attempted using forceps or similar non-sharp objects. Cleaning may be attempted, if required, using a dry lint-free cloth. If the insides of the patient circuit tubing ports cannot be cleaned, DO NOT attempt to use the SAVe; the SAVe should be sent to the manufacturer for refurbishment and testing. To prevent debris from entering the SAVe, the patient port covers should always be securely in place when the unit is not in use or being cleaned. Patient circuit tubing connections should be wiped with a damp cloth and dried using a lint-free cloth. Carefully clean the port covers with a damp cloth and dry using a lint-free cloth. The exterior housing of the SAVe may be cleaned as necessary using a

damp cloth and dried using a lint- free cloth. The front panel of the SAVe should be cleaned as necessary using only a lint-free cloth. DO NOT expose the switch, external power jack, or audible alarm port directly to liquids.

Do not clean any portion of the SAVe or its accessories with abrasives or chlorinated hydrocarbon cleansers.

Debris Filter: The debris filter should be replaced with a new filter following each use. Should the debris filter require cleaning during use, and a new filter is unavailable, the debris filter may be cleaned using a dry, lint-free cloth. Use a cleaning motion from the center of the filter outwards, taking care not to rip or otherwise damage the filter. A damaged debris filter should not be used. Clean both sides of the filter. The debris filter is not to be intentionally exposed to fluids or other cleaning agents. Reinstall the filter following cleaning per directions for the installation of a debris filter.

Patient Mask: Wash and scrub the patient mask in warm soapy water. Rinse in clean water. Submerge for 10 minutes in a 1:64 household bleach : water solution. Rinse again and allow to dry. DO NOT pasteurize, boil, gas, or steam mask. NOTE: If mask becomes sticky, clean as recommended above.

Patient Circuit: Patient tubing and valves must be replaced prior to use on a new patient. Do not unpack accessories for the patient circuit until system is to be used. Examine the tubes for cracking, discoloration, sharp edges, or other signs of damage. If necessary, exterior walls of tubing may be cleaned with a damp cloth and dried using a lint-free cloth. DO NOT attempt to use or repair damaged patient circuits. Replace damaged patient circuits.

Storage Instructions

Prior to storing the SAVe unit, ensure that the unit is fully charged. Storing the unit in a discharged state will be detrimental to the internal battery.

For extended storage periods, the SAVe should be stored indoors, out of direct sunlight, and in a clean environment. The best storage temperature is between 10 and 30 degrees Celsius (50 to 80 degrees Fahrenheit). For short-term storage, the temperature can range from -5 to 40 degrees Celsius (20 and 104 degrees Fahrenheit). In both cases, the relative humidity in the storage facility should be low. At temperatures below freezing, the device may malfunction and will likely deliver less tidal volume than stated during the first couple of minutes of operation. Operating the SAVe in temperatures below freezing may permanently damage the device.

It is recommended that the SAVe unit is recharged as directed by the chart below every 6 months to ensure optimum performance when the device is needed.

Storage Temperature	Interval of charge (refresh charge)
Below 68^{o}F (20^{o}C)	9 Months
68F (20^{o}C) to 86^{o}F (30^{o}C)	6 Months
86^{o}F (30^{o}C) to 104^{o}F (40^{o}C)	3 Months

Expected failure time and mode and its effect on the patient

The internal pump of the SAVe is the first expected component to fail over the life of the unit. This is expected to occur following 2,000 to 3,000 hours of ventilator use. When the pump fails, the "device alarm" will be triggered (please see section: Device Errors (non-field serviceable). The ventilator will cease pumping air to the patient and will alarm immediately. The medic should replace the dysfunctional unit immediately or begin rescue breathing.

Instructions on how to safely dispose of the device

If the SAVe unit is no longer in use, it should be mailed back to AutoMedx's facilities for proper disposal. Please contact AutoMedx for packaging and mailing instructions.

Instructions on accessories

All accessories should be kept in their original packaging as sent from AutoMedx until they are to be used. Any accessory in an open or torn bag should not be used and should be discarded. With the exception of the power supply, all of the accessories are for single patient use. The $EtCO_2$ should be changed every hour. Each accessory from AutoMedx will come with its own set of instructions on proper use. The SAVe is only to be used with accessories pre-approved by AutoMedx. The patient breathing circuit and accompanying accessories are all "Type-B" parts under 60601-1; this means these are applied parts that are not conductive and can immediately be released from the patient.

Troubleshooting

Ensure that the light indicators are not suppressed while troubleshooting.

Patient Alarms

Please note once the problem that triggered the alarm is fixed, the alarm will cease and the ventilator will begin proper operation on its own.

1) The ventilator motor repeatedly tries to start but quickly stops. There is a blockage (begin with the vent and work towards patient)
    a. Ensure intake port is not blocked.
    b. Ensure patient tubing isn't kinked.
    c. Ensure there is no debris in the patient circuit valve.
    d. If using a mask
        i. Ensure head is tilted back.
        ii. Ensure there is no debris or vomitus in mouth or mask.
    e. If using an ET Tube
        i. Ensure tube is properly placed in trachea.
        ii. If $ETCO_2$ detector is being used, verify that proper gas exchange is occurring. If not, ET Tube may be in the stomach.
    f. Repeat process.
    g. If problem is not identified, replace patient circuit.
    h. If problem persists, ventilate patient by other means or begin rescue breathing.

2) The ventilator motor turns on for a couple of seconds and then is off for a couple of seconds. Aside from the alarm, the device seems to function normally. This is indicative of a leak or disconnect.
    a. This alarm could be triggered by a leak in the patient's lungs. If that is not the case, follow the trouble shooting suggestions below.
    b. Ensure both tubes going to patient are properly connected to the ventilator.
    c. If using a mask, make sure there is a tight seal to the patient's face.
    d. If using an ET Tube, ensure it's not dislodged.
    e. Ensure patient tubing is connected to the ET Tube or mask.
    f. Ensure there is no hole or leak in the patient circuit. If leak is found replace immediately.
    g. If problem is not identified, replace patient circuit.
    h. If problem persists, ventilate patient by other means or begin rescue breathing.

3) If the ventilator cuts off for more than 10 seconds, the exhaust valve is malfunctioning, replace patient breathing circuit immediately.

4) Intermittent alarm signifies that stacking is occurring (insufficient amount of air is being exhaled from the lungs between breaths). When this is occurring, the alarm will be on while the pump is off. This will occur for a number of seconds. As air is released, the alarm will cease and pump will resume. This cycle may repeat itself every several breaths.

a. Ensure that the exhaust valve is not occluded.
b. If problem is not identified, replace patient circuit.
c. If problem persists, ventilate patient by other means or begin rescue breathing.

Device Alarms

1) Turn device off for a few seconds and then back on.
2) If problem persists, ventilate patient by other means or begin rescue breathing.

Battery Alarms

1) Low Power
   a. Once the bottom battery light begins to blink, ventilator has approximately 45-60 minutes of battery life.
   b. Connect unit to charger if available.
   c. Be prepared to replace unit or otherwise ventilate patient.

2) Temperature Alarm
   a. If all four battery lights are blinking, the internal temperature is too high. Ventilator may not operate properly.
   b. Replace unit if possible.
   c. If another unit is unavailable, ventilate patient by other means or begin rescue breathing.

Limited Warranty

Limited Warranty Applicable to the SAVe
AutoMedx warrants to the original purchaser ("Customer") of the SAVe that if there is a defect in material or workmanship in the SAVe and AutoMedx is notified of such defect within one (1) year of Customer's original purchase, AutoMedx shall, in its sole and absolute discretion, repair or provide a replacement of such defective part(s) at no charge to the Customer, provided that this warranty provision is not applicable to batteries or used consumables.

Limited Warranty Applicable to the Battery
The life of the battery, as noted in the section of the User Manual, entitled "Battery Power Level and High Temperature Indicator," is materially affected by many factors. As such, AutoMedx warrants to the Customer of the SAVe that, if there is a defect in material or workmanship in the battery contained in the SAVe and AutoMedx is notified of such defect within ninety (90) days of Customer's original purchase, AutoMedx shall, in its sole and absolute discretion, repair or provide a replacement of such defective battery at no charge to the Customer.

Maintenance
Mechanical components are subject to wear and fatigue over time. In compliance with the operating specifications in this User Manual, it is the user's responsibility to follow the instructions in the section entitled, "Cleaning and Maintenance." Among other things, after 2000 hours of use or 1 year, whichever comes first, the SAVe must go through a complete testing process to ensure continued operation within the specifications. The testing must be completed by an AutoMedx certified facility.

Sole Remedy
The sole remedy for a defect in materials or workmanship of the SAVe (or the battery or any other component of the SAVe) shall be, at AutoMedx's sole and exclusive discretion, repair or replacement of the defective SAVe or component thereof, as the case may be.

Exclusions
AutoMedx's warranty shall not apply to defects or conditions resulting from: (a) repairs by an unauthorized party; (b) improper maintenance; (c) modifications made without written permission of AutoMedx; (d) damage by accident, abuse, misuse, or misapplication; or (e) operation otherwise than in accordance with this User Manual or other instructions furnished by AutoMedx.

AutoMedx's warranty shall not apply if the unit has been disassembled. AutoMedx's warranty shall not apply to: (a) any Product if the serial number of such Product has been altered, defaced or removed or (b) any used consumables.

All warranty repairs shall be subject to return postage billing.

DISCLAIMER OF WARRANTY AND LIMITATION ON REMEDIES

THE WARRANTY AND REMEDIES SET FORTH ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHERS, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED. AUTOMEDX SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

AUTOMEDX IS NOT RESPONSIBLE FOR DIRECT, INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY.

Accessory Re-Order Information

Please contact AutoMedx at phone number 301-916-9508 to re-order any accessory.

The SAVe is only to be used with accessories pre-approved by AutoMedx, found in the table below.

Part #	Description
M40003	Ruggedized Patient Breathing Circuit
E10492	ResQStrap
E10491	Re-useable Mask
F20022	SAVe - Soft Carrying Case
E10477	Et-CO2 Detector
M40037	Debris Filter (pack of 5)
E10478	Battery Charger

PRODUCT SPECIFICATIONS

Model 550x10

BATTERY LIFE:	up to 5.75 hours
WEIGHT:	3.1 pounds
SIZE:	6.75” x 6.25” x 2.5”
TIDAL VOLUME:	550 +/-55 mL/breath
RESPIRATORY RATE:	10 BPM
PEAK INSPIRATORY PRES	30 cmH_2O

Model 600x10

BATTERY LIFE:	up to 5.5 hours
WEIGHT:	3.1 pounds
SIZE:	6.75” x 6.25” x 2.5”
TIDAL VOLUME:	600 +/-60 mL/breath
RESPIRATORY RATE:	10 BPM
PEAK INSPIRATORY PRES	38 cmH_2O

FEATURES

- Ease Of Use: Single knob operation
- Does NOT require compressed gas source
- System can accept supplemental air
- Prevents over-inflation of lungs
- Fail-safe mechanisms and visual/audible alarms
- Detects airway blockage
- Consistent tidal volume and respiratory rate
- Threshold detector for $EtCO_2$ in patient exhale (see page 24)

ADVANTAGES

- Fills an underserved need in emergency resuscitation
- Compact design makes it highly portable
- Very little training required
- Does not rely on software
- Quick turn around between patients
- Disposables prevent cross contamination
- Long shelf life and durability
- Ideal for remote/austere locations
- Hands free design reduces manpower requirements

AutoMedx, Inc.

Simplified Automated Ventilator

Operations Manual

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M40032

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